DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 12, 2015

HEARTWAY Medical Products Co., Ltd.
c/o Jen Ke-Min
No.6 Road 25, Taichung Industrial Park
Taichung City, TW 40850

Re: K142783
Trade/Device Name: HEARTWAY Electrically Powered Wheelchair P27
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: May 12, 2015
Received: May 20, 2015

Dear Jen Ke-Min,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142783

Device Name
HEARTWAY Electrically Powered Wheelchair P27

Indications for Use *(Describe)*
The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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HEARTWAY

510(k) SUMMARY

Submitter's Name:	***HEARTWAY Medical Products Co., Ltd.***
	No.6, Road 25, Taichung Industrial Park, Taichung, 40850, Taiwan, ROC
	TEL: 886-4-23580357 / 886-4-23583232
	FAX: 886-4-23590786
Date summary prepared:	March 20, 2015
Device Name	
Proprietary Name:	HEARTWAY Electrically Powered Wheelchair, Model P27
Common or Usual Name:	POWERED WHEELCHAIR
Classification Name:	Powered Wheelchair, Class II, 21 CFR 890.3860
Product Code:	ITI
Company contact:	Mr. Yang, T. H. (yhead0722@hotmail.com)
Official Correspondent:	Dr. Jen, Ke-min (ceirs.jen@msa.hinet.net)
Predicate device	K070489 Heartway Power Tilt Seating System Power Chair, P16RT

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Description of the device:

The HEARTWAY Electrically Powered Wheelchair, Model P27 is battery powered and configured with 2 PU solid front castors and 2 pneumatic **rear drive wheels**, a width adjustable seat, a controller to control the lighting function and driving function, a main frame, a foot-rest, a pair of arm-rest, a back-rest, a seat cushion, a pair of skirts, a set of anti-tippers.

P27 powered wheelchair is **rear-wheel driven** and operated by two pneumatic rear wheels as the drive wheels, two solid front wheels as the front casters and uses upper joystick to control the driving direction, driving speed, and lighting function. Main frame carries a width adjustable seat system and a set of anti-tipper to prevent a patient from tipping their wheelchairs backward. Main frame is equipped with the front & rear independent suspensions to enhance the stability. A width-adjustable seat system carries a set of back rest system, a seat cushion, a pair of arm-rest, a pair of foot-rest, and a pair of skirts to provide seat posture positioning functions. P27 power wheelchair maximum weight capacity is 265 lbs (120kg). Maximum speed is 3.75 mph (6 kph). The device can be disassembled for transport and is provided with an external battery charger.

Performance Testing:

1) EMC Report ANSI / RESNA WC/Vol.2: 2009 (Section 21), CISPR 11: 2004+A2:2006, EN61000-4-2: 2008, IEC61000-4-3: 2006, IEC61000-4-8: 2001 (Electrically powered wheelchairs, scooters, and their chargers – requirements and test methods).
2) ISO 7176-1 Wheelchairs - Part 1: Determination of static stability, 1999.
3) ISO 7176-2 Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs, 2001.
4) ISO 7176-3 Wheelchairs - Part 3: Determination of effectiveness of brakes, 2012.
5) ISO 7176-4 Wheelchairs - Part 4: Energy consumption of electric wheelchairs for determination of theoretical distance range, 2008.
6) ISO 7176-5 Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space, 2008.
7) ISO 7176-6 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs, 2001.
8) ISO 7176-7 Wheelchairs - Part 7: Determination of seating dimensions - Definitions and measuring method, 1998.
9) ISO 7176-8 Wheelchairs - Part 8: Static, impact and fatigue strength for manual wheelchairs, 1998.
10) ISO 7176-9 Wheelchairs - Part 9: Climatic tests for electric wheelchairs, 2009.
11) ISO 7176-10 Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs, 2008.
12) ISO 7176-11 Wheelchairs - Wheelchairs - Part 11: Test dummies, 2012.
13) ISO 7176-13 Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces, 1989.

14) ISO 7176-14 Power and control system for electric wheelchairs, 2008.
15) ISO 7176-15 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labelling, 1996.
16) ISO 7176-16 Requirements and test methods for resistance to ignition of upholstered parts, 2012.
17) ISO 7176-21 Requirements and test method electromagnetic compatibility of powered wheelchairs and motorized scooters, 2009.

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HEARTWAY

COMPARISON TABLE

ITEMS	PREDICATE DEVICE	SUBJECT DEVICE	Safety and effectiveness of subject device compared to the predicate device
Brand name	*HEARTWAY*		Same brand
Manufacturer	*HEARTWAY Medical Products Co., Ltd.*		Same manufacture
Series	Power Tilt Seating System power chair	Electrically Powered Wheelchair	Different design
Model	P16RT	P27	Different models
510K number	K070489	K142783	Different submissions
Similarities			
Intended use	*The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.*	*The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.*	Same intended use
Frame Type Material	Folded Carbon steel alloy	Folded Carbon steel alloy	Same material
Footplates	ABS	ABS	Same material
Back upholstery	Fabric	Fabric	Same material
Armrest types	Flip-backward	Flip-backward	Same type
Wheel Lock	Push-to-Lock	Push-to-Lock	Same type
Suspension	Cross brace	Cross brace	Same type

Seat tilting function	Yes	Yes	Same function
Patient contacting material	Seat PVC material Hand grip PVC material Safety belt PVC material	Seat PVC material Hand grip PVC material Safety belt PVC material	Same material
Electronic controller	PG VR2 70 Amp	PG VR2 70 Amp	Same controller
Anti-tipper	Yes	Yes	Same function
Biocompatibility	**ISO 10993-1** **ISO 10993-5**	**ISO 10993-1** **ISO 10993-5**	Same biocompatibility
Warranty	**3 years**: Main frame **1 years**: Controller / gear motor / batteries w/o exhaustive and wear parts	**3 years**: Main frame **1 years**: Controller / gear motor / batteries w/o exhaustive and wear parts	Same warranty
Differences			
Maximum speed	9.6km/h(6 mph)	6 km/h(3.75 mph)	Smaller speed
Maximum user weight capacities	500 lbs / 225 kg	265 lbs/120 kgs	Smaller weight
Overall dimension **Overall length** **Overall width** **Overall height**	 1150 mm / 45” 660 mm / 26” 1170 mm / 46”	 1030 mm / 40.5” 870-1420 mm /34.2”-55.9” 1250 mm / 49.2”	 Smaller Length Larger width Larger height
Batteries **Quantity** **Type** **Range per charge**	 Two 50Ah 12VDC 35km / 21.8 miles	 Two Same 32km / 20 miles	 Same Same type Smaller range

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Rear wheels **Quantities** **Sizes/type**	2 14.0" *3"x 2 (PU solid tire)	2 12.4"x2.16"x2 (Pneumatic tire)	Smaller rear tires
Casters	9.5" *3" x 2 (PU solid tire)	7.48"x1.77"x2 (PU solid tire)	Smaller castors
Seat size **Width** **Depth** **Height**	66 cm / 25.9" 87 cm / 34.2" 41 cm / 16.1"	46 cm / 18" 47 cm / 18.5" 49-60cm / 19.3"-23.6"	Smaller seat width & depth Larger seat height
Backrest reclining function	No	Yes	Smaller incline angle
Curb climbing	65 mm/2.5"	50 mm/1.96"	Smaller curb
Dynamic incline angle	12 degrees	6 degrees	Smaller incline angle
Ground clearance	80 mm/3.15"	50 mm/1.96"	Smaller clearance
Turning radius	610mm/24"	730 mm/28.7"	Larger turning radius
Motor **Quantity** **Type**	2 24V, 500W	2 24V, 200W	Same Smaller power
Wheelchair Weight	w/ batteries 114kg / 251 lbs w/o batteries 84kgs /185 lbs	w/ batteries 90 kgs / 198 lbs w/o batteries 60 kgs / 132 lbs	53 lbs frame difference
Charger	24VDC (UL 1310)	24VDC (UL E201162)	Different UL –certified chargers

COMPARISON DISCUSSION

For the maximum user weight capacity, wheelchair total weights, cruise range per charging and maximum speed, the subject device are smaller than the predicate device. The facts show the subject device is designed to perform in a lighter weight way than the predicate device. In order to function in a lighter weight design, rear wheels sizes and front castors sizes of the subject device can be smaller than those of the predicate device. To drive a lighter wheelchair with a slower maximum speed, the motor powers of the subject device can be smaller than those of the predicate device, based on the work-energy theorem. Since the motor powers and the maximum speed of the subject device are smaller than those of the predicate device, the cruise range is smaller according to the definition of work. These differences are only related to the designing aspects and not related to the safety and effectiveness aspects.

Owing to the smaller wheels and castors, the ground clearance and curb climbing of the subject device are smaller than those of the predicate device. As for the larger turning radius for the subject device, it is due to the larger overall width of the subject device. But the subject device passes the ISO 7176 series standards, the static and dynamic stabilities are all assured. Thus different radius and different widths do not raise any safety and effectiveness aspects. They are substantially equivalent.

The overall height and seat height of the subject device are larger than those of the predicate device. The subject device performs in a lighter weight design and has a backrest reclining function and a less maximum user weight capacity, the center of gravity of the subject device is higher than that of the predicate device. The fact results in smaller incline angle of the subject device 6 degrees, compared with 12 degrees of the predicate device. After all, two devices all pass the ISO 7176-2 standard; the dynamic stabilities of two devices are all assured. And this 6 degrees limitation is shown in the P27 user's manual for safety operation. There are no safety and effectiveness concerns. They are substantially equivalent with respect to these differences.

The battery chargers are different model but are the same 24 VDC type. Two chargers are UL-certified and there are no safety and effectiveness hazards. The difference does not raise any safety and effectiveness aspects concerned.

Despite of the above differences, the two devices all completed the performance tests in accordance with ISO 7176 series standards and the ANSI / RESNA WC 2, Section 21 for the EMC test. They function safely and effectively. There are no safety and effectiveness aspects concerned. Thus, the two devices are substantially equivalent.

CONCLUSIONS

The subject device, HEARTWAY Electrically Powered Wheelchair, Model P27, is as safe and effective as, and functions in a manner equivalent to the K070489 predicate device, HEARTWAY *Power Tilt Seating System power chair* P16RT. The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus the subject device is substantially equivalent to the predicate device.